2009 H1N1 Influenza
Updated Key Points
December 15, 2009

2009 H1N1 Influenza Vaccine

In this Section:

Announcements

- **(New)** As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its 2009 influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can be reduced over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one batch (called a "lot") of vaccine in pre-filled pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while filled at the the proper level at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots.

- National Influenza Vaccination Week (NIVW) is a national initiative that was established to highlight the importance of continuing influenza vaccination, as well as to foster greater use of flu vaccine after the holiday season into January and beyond. This year's NIVW, originally scheduled for December 6-12, 2009, is now rescheduled to January 10-16, 2010. Updates will be provided as more information becomes available.

- We hope that all of our partners will plan their own NIVW events and share their plans with us at www.flu.gov and http://www.cdc.gov/flu/NIVW/form.htm.

- **(New)** Webcast for Health Care Providers: Join us December 16, 12-1 p.m. ET, as experts from the U.S. Department of Health and Human Services and the former president of the American Medical Association answer your questions about the 2009 H1N1 virus and vaccine. The webcast is hosted by the HHS and will be live on www.flu.gov. Join the discussion by sending questions or comments to hhsstudio@hhs.gov.

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- HHS has joined with the Ad Council to launch a new nationwide Public Service Announcements (PSA) campaign called *Together We Can All Fight the Flu* that encourages Americans to get vaccinated against the 2009 H1N1 flu virus. The PSAs are now available for various audiences at www.flu.gov.

Supply

- On November 16, 2009, the Food and Drug Administration (FDA) announced its approval of a fifth vaccine for protection against the 2009 H1N1 flu virus. This vaccine will be manufactured using the same established, licensed egg-based process that is used for producing seasonal flu vaccine and will be produced in multi-dose vials, in a formulation that contains thimerosal. Since this vaccine will not be available for distribution until the end of December, it does not affect current vaccine supply.

- **(Updated)** As of Monday, December 14, 2009, a total of 92,883,100 doses were available for ordering. Of those available doses, 72,144,500 doses were injectable (flu shots) and 20,738,600 were LAIV (nasal spray vaccine).

- **(Updated)** As of Monday, December 14, 2009, there were a total of 80,696,800 doses ordered and total of 76,355,920 doses shipped.

- The further delivery of Sanofi Pasteur 7.5 microgram prefilled syringes is delayed indefinitely due to release issues at the manufacturer.

- Supplies of 2009 H1N1 vaccine continue to increase. More doses are expected for shipment each week. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine continues to become available.

Recommendations

- Parents are now encouraged to seek the second dose of 2009 H1N1 vaccine for their children who are younger than 10 years old. The recommended interval between the first and second dose should be at least 28 days; however, a second dose given at least 21 days after the first is considered valid.

Flu Activity May Occur in "Waves"

- The timing, spread and severity of influenza viruses is uncertain.
- Outbreaks of influenza may occur in different places at different times.

- Outbreaks may occur in waves of about 6-12 week time periods.
- These waves of influenza may occur over a year or so after the emergence of a new influenza virus.
- In past pandemics, "waves" of activity have been observed.
- The first wave is usually a smaller wave; followed by a larger "peak" wave. Subsequent smaller waves can occur as well.
- The United States experienced its first wave of 2009 H1N1 pandemic activity in the spring of 2009.
- At this time, we are experiencing a second wave of 2009 H1N1 activity.
- It's possible that other waves of influenza activity may occur after this current wave – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- Because the timing and spread of influenza viruses are unpredictable, CDC is continuing to recommend vaccination with seasonal influenza vaccine and 2009 H1N1 vaccine for those people in whom it is recommended.

2009 H1N1 Influenza Vaccine Safety

- Getting the 2009 H1N1 influenza vaccine is much safer than getting H1N1 influenza. You can prevent 2009 H1N1 influenza illness by getting the 2009 H1N1 vaccine.
- The benefits of getting the 2009 H1N1 influenza vaccine far outweigh the very small risk of serious complications from vaccination. Some people getting vaccinated will have mild side effects such as pain, redness or swelling in the arm where the shot was given or a runny nose and headache after the nasal spray vaccine.

MMWR: Monitoring the Safety of Influenza A (H1N1) 2009 Monovalent Vaccines in the United States, Preliminary Findings

- In this MMWR, published December 4, 2009 CDC reports on the preliminary safety results for the 2009 H1N1 influenza vaccines from the first months of reports received through the U.S. Vaccine Adverse Event Reporting System (VAERS), a national surveillance system and data from the Vaccine Safety Datalink.
- The VAERS database was searched to identify all U.S. reports received of adverse events following vaccination with 2009 H1N1 vaccines and 2009 seasonal influenza vaccines from July 1, 2009 through November 24, 2009.

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- Data from VAERS show that in post-licensure monitoring, the overall reporting rate after 2009 H1N1 vaccination is higher than that for seasonal influenza vaccination. Although this might represent an actual difference in safety, increased reporting rates are expected due to the efforts to enhance reporting to VAERS and the heightened public awareness of the 2009 H1N1 vaccine.

- As of November 24, 2009, nearly 52 million doses of 2009 H1N1 vaccine had been shipped to vaccination providers in the United States.

- As of November 24, 2009, VAERS had received 3,783 adverse event reports following 2009 H1N1 vaccination.

- The vast majority (95%) of adverse events reported to VAERS after receiving the 2009 H1N1 vaccine were not serious (e.g., soreness at the vaccine injection site).

- Of the 3,783 reports, 204 (5%) were reports that involved what would be considered serious health events (defined as life threatening or resulting in death, major disability, abnormal conditions at birth, hospitalization, or extension of an existing hospitalization).

- The percentage of reports involving what would be considered serious health events is not substantially different between 2009 H1N1 and seasonal influenza vaccines. Additionally, no new or unusual events or pattern of adverse events have emerged. VAERS reports continue to be monitored as more vaccine is administered.

- Among the 204 reports of serious health events after H1N1 vaccination, there were 13 reports of death.

- The 13 VAERS reports that involve deaths are under review by CDC, FDA and the states where the reported deaths occurred. Preliminary findings do not indicate a common cause or pattern (such as similarities in age, gender, geographic location, illness surrounding death, or underlying medical conditions) to suggest that these deaths were associated with the vaccine. These cases are under further review pending additional medical records (e.g. autopsy reports, medical files).

- VAERS received 10 reports of Guillian-Barré syndrome (GBS) of which follow-up assessments are underway. An additional 2 reports describing neurologic events are also under review as possible GBS. In the United States, about 80-160 cases of GBS are expected to occur each week, regardless of vaccination.

- Eleven (11) reports of anaphylaxis were received by VAERS; an additional 8 reports of possible anaphylaxis were identified. Of these 19, 13 met Brighton Collaboration case definition criteria, five had an anaphylaxis diagnosis on medical record review, and one has not been confirmed. These 19 reported cases of anaphylaxis are not at a rate above the background rate for this adverse event.

- CDC has enhanced vaccine safety monitoring efforts in several ways:

    - The Vaccine Adverse Event Reporting System (VAERS) is a voluntary reporting system that identifies potential vaccine safety signals: healthcare providers are actively reminded to report clinically significant adverse events after vaccination, even if they are not sure if the vaccine caused the adverse event, and medical personnel are conducting daily reviews and follow-up [http://vaers.hhs.gov].

    - Second, a new Web-based active surveillance system is being implemented to prospectively follow tens of thousands of vaccinated people [www.myflushot.org].

    - Third, large population-based systems that link computerized vaccination data with healthcare codes are being used to conduct rapid and ongoing analyses. This approach includes data from large managed care plans, other health plans, Department of Defense, Medicare and the Veterans' Administration.

    - Fourth, active case finding for Guillain-Barré syndrome (GBS) is being conducted in 10 areas of the United States (a combined population of about 45 million people).

- Findings from all sources are cross-referenced and reviewed by government and outside scientists to be sure any concerns are rapidly addressed.

In this Section:

Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that more individuals have been vaccinated with seasonal vaccine this season than at the same time last year. This is most likely due to the early availability of vaccine and public interest in getting vaccinated.

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- Due to early availability and high demand of seasonal flu vaccine, limited amounts of seasonal supply remain. At this point, CDC continues to encourage those at highest risk from flu complications to seek seasonal flu vaccine and receive 2009 H1N1 vaccine, as recommended.
- **(Updated)** As of December 4, 2009, approximately 110.6 million doses of vaccine have been distributed (96% of the doses expected this season).
- Local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (http://www.preventinfluenza.org/ivats/) over the coming weeks.

More information about seasonal flu vaccine supply can be found at:
http://www.cdc.gov/flu/professionals/vaccination/#supply